UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,320	12/11/2001	Siamak Tabibzadeh	50425/137	1488

7590 10/03/2006

Craig J. Arnold
Amster, Rothstein & Ebenstein
90 Park Avenue
New York, NY 10016

EXAMINER	
YAEN, CHRISTOPHER H	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 10/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/014,320	TABIBZADEH, SIAMAK	
	Examiner	Art Unit	
	Christopher H. Yaen	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-26* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Re: TABIBZADEH, SIAMAK

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 9-10, drawn to a method of determining whether a subject has pre-neoplastic or neoplastic lesion in transitional epithelial cells comprising assaying with an antibody to ebaf, classified in class 435, subclass 7.1, for example.

   II. Claims 11-13, drawn to a method of determining whether a subject has pre-neoplastic or neoplastic lesion in transitional epithelial cells comprising assaying with nucleic acid probes which hybridize to a nucleic acid encoding ebaf, classified in class 435, subclass 6, for example.

Claims 1-8 link(s) inventions I and II. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 1-8. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is

earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

III. Claims 19-20, drawn to a method of assessing the efficacy of therapy to treat preneoplatic or neoplastic lesions in transitional epithelial cells in a subject undergoing treatment for pre-neoplastic or neoplastic lesion in transitional epithelial cells comprising assaying diagnostic samples with an antibody to ebaf, classified in class 204, subclass 450, for example.

IV. Claims 21-23, drawn to a method of assessing the efficacy of therapyto ptreat preneoplatic or neoplastic lesions in transitional epithelial cells in a subject undergoin treatment for pre-neoplastic or neoplastic lesion in transitional epithelial cells comprising assaying diagnostic samples with an nucleic acid probes which hybridize to a nucleic acid sequence encoding ebaf, classified in class 435, subclass 5, for example.

Claims 14-18 link(s) inventions I and II. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 14-18. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

V. Claims 24-26, drawn to a method of assessing the prognosis of a subject who has a pre-neoplastic or neoplastic lesion comprising assaying a diagnostic sample of the subject for protein expression, classified in class 436, subclass 501, for example.

VI. Claims 24-26, drawn to a method of assessing the prognosis of a subject who has a pre-neoplastic or neoplastic lesion comprising assaying a diagnostic sample of the subject for nucleic acid expression, classified in class 436, subclass 94, for example.

2. The inventions are distinct, each from the other because of the following reasons: Inventions I-VI are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the specification does not disclose that these methods would be used together. The method of determining whether a subject has a pre-neoplastic or neoplastic lesion comprising the assaying of ebaf expression with an antibody (group I), the method of determining whether a subject has a pre-neoplastic or neoplastic lesion comprising the assaying of ebaf expression with nucleic acid probes which hybridize to a nucleic acid sequence which hybridizes to a nucleic acid which encodes ebaf (group II), a method of assessing the efficacy of therapy to treat preneoplatic or neoplastic lesions in transitional epithelial cells in a subject undergoing treatment for pre-neoplastic or neoplastic lesion in transitional epithelial cells comprising assaying diagnostic samples with an antibody to ebaf (group III), a method of assessing the efficacy of therapyto ptreat preneoplatic or neoplastic lesions in transitional epithelial cells in a subject undergoin treatment for pre-neoplastic or neoplastic lesion in transitional epithelial cells comprising assaying diagnostic samples with an nucleic acid probes which hybridize to

a nucleic acid sequence encoding ebaf (group IV), a method of assessing te prognosis of a subject who has a pre-neoplastic or neoplastic lesion comprising assaying a diagnostic sample of the subject for protein expression (group V), and a method of assessing the prognosis of a subject who has a pre-neoplastic or neoplastic lesion comprising assaying a diagnostic sample of the subject for nucleic acid expression (group VI)are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention have different outcomes and are performed for different reasons. Moreover, the methodology and materials necessary for determining the protein expresson of ebaf differs significantly from the method of assessing nucleic levels or expression of ebaf. Therefore, each method is divergent in materials and steps. For these reasons the Inventions I-VI are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups I- VI have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups I-VI together.

3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher Yaen
Art Unit 1643
September 28, 2006

CHRISTOPHER H. YAEN
PRIMARY EXAMINER